8-22-99

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DATA EVALUATION RECORD

PROHEXADIONE CALCIUM TECHNICAL
(BX-112)

Study Type: §81-4; Primary Eye Irritation

Work Assignment No. 1-02-25KK (MRID 44457745)

Prepared for
Health Effects Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Crystal Mall II
Arlington, VA 22202

Prepared by
Pesticide Health Effects Group
Sciences Division
Dynamac Corporation
2275 Research Boulevard
Rockville, MD 20850-3268

Primary Reviewer:
Christie E. Padova, B.S.

Signature: Christie E. Padova
Date: 6-22-99

Project Manager:
Mary L. Menetrez, Ph.D.

Signature: Mary L Menetrez
Date: 6/28/99

Disclaimer

This Data Evaluation Record may have been altered by the Health Effects Division subsequent to signing by Dynamac Corporation personnel.

EPA Reviewer: Albin Kocialski, Ph.D.
Registration Action Branch 2 (7509C)

For A K Murphy 8/22/99

Work Assignment Manager: Sanjivani Diwan, PhD for S D Murphy 8/22/99
Toxicology Branch 1 (7509C)

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit
OPPTS Number: 870.2400 OPP Guideline Number: §81-4

DP BARCODE: D246707 SUBMISSION CODE: S543930
P.C. CODE: 112600 TOX. CHEM. NO.: None

TEST MATERIAL (PURITY): Prohexadione calcium technical (89.8% purity)

SYNONYMS: BX-112; calcium salt of 3,5-dioxo-4-propionylcyclohexane-1-carboxylic acid; KIM-112; KUH-833

CITATION: Jones, J. (1988) BX-112 technical: acute eye irritation test in the rabbit. Safepharm Laboratories Limited, Derby, U.K. Laboratory Project Number 131/38. December 1, 1988. MRID 44457745. Unpublished.

SPONSOR: BASF Corporation, P.O. Box 13528, Research Triangle Park, NC.

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 44457745), a 81-mg portion (0.1-mL equivalent) of prohexadione calcium technical (89.8% purity) was placed into the conjunctival sac of the right eye of three young adult New Zealand White rabbits. Animals were observed for ocular irritation for up to 72 hours following instillation.

Positive ocular irritation, characterized by iridial effects (scores of 1) and moderate conjunctival redness (scores of 2) was observed in 2/3 treated eyes 1 hour following instillation. No corneal effects were observed, and all iridial and conjunctival irritation (positive and otherwise) subsided by 24 hours. In this study, **prohexadione calcium technical is a mild ocular irritant**, and is classified as **TOXICITY CATEGORY IV** based on the subsidence of all ocular irritation by 24 hours.

This study is classified **acceptable (§81-4)** and satisfies the guideline requirement for a primary dermal irritation study in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: Prohexadione calcium technical (BX-112)
   Description: Cream-colored powder
   Lot/Batch #: G14-04
   Purity: 89.8%
   CAS #: 127277-53-6

2. Vehicle: None employed

3. Test animals: Species: Rabbit
   Strain: New Zealand White
   Age: Young adult (12-16 weeks)
   Weight: 2.63-3.22 kg (combined sexes)
   Source: David Percival Ltd., Moston, Sandbach, Cheshire, U.K.
   Acclimation period: ≥5 Days
   Diet: Rabbit Diet, Preston Farmers Limited, New Leake, Boston, Lincolnshire, U.K., ad libitum
   Water: Tap water, ad libitum
   Housing: Individually in suspended metal cages
   Environmental conditions:
   Temperature: 14-19 °C
   Humidity: 64-70%
   Air changes: 15/Hour
   Photoperiod: 12-hour light/dark cycle

B. STUDY DESIGN and METHODS:

1. In-life dates: September 27 - October 1, 1988

2. Animal assignment and treatment: A 81-mg portion (0.1-mL equivalent) of prohexadione calcium technical was placed into the conjunctival sac of the right eye of three young adult New Zealand White rabbits (one male and two female). The left eye of each animal served as an untreated control. The animals were observed for ocular irritation at 1, 24, 48, and 72 hours following instillation. Ocular irritation was graded using the Draize scale for ocular lesions.

II. RESULTS AND DISCUSSION:

A. Clinical observations: The incidence of positive ocular irritation is presented in Table 1. One hour following instillation, iridial changes (score of 1) were observed in 2/3 treated eyes; slight conjunctival redness (score of 1) was observed in 1/3 eyes and moderate redness (score of 2) was observed in 2/3 eyes; very slight conjunctival chemosis (score of 1) was observed in 3/3 eyes; and slight conjunctival discharge (score of 1) was observed in 1/3 eyes. No corneal effects were observed, and all ocular irritation (positive and otherwise) subsided by 24 hours. In this study, prohexadione calcium technical is a mild ocular irritant.

TABLE 1. Incidence of Positive Ocular Effects

Observations	Number "Positive"/Number Tested			
	Hours			
	1	24	48	72
Iris	2/3	---	---	---
Conjunctivae				
Redness	2/3	---	---	---
Chemosis	---	---	---	---
Discharge[a]	---	---	---	---

--- No positive observations.

[a] Discharge is not included in evaluating a positive reaction; however, scores of ≥2 are included in this table.

B. Deficiencies: There were no deficiencies that affected the results of this study.